IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF VIRGINIA Roanoke Division

ONCOLOGY AND HEMATOLOGY ASSOCIATES OF SOUTHWEST VIRGINIA, INC., a Virginia Corporation, dba BLUE RIDGE CANCER CARE,))))
Plaintiff,)
v.) Civil Action No. 7:16cv_00269
GENENTECH INC., a Delaware Corporation,) Jury Trial Demanded)
Serve: Corporation Service Company Registered Agent 115 SW 89 th Street Oklahoma City, OK 73139, Defendant.))))))))

COMPLAINT

Plaintiff Oncology and Hematology Associates of Southwest Virginia, Inc., for its Complaint against defendant, Genentech Inc. ("Genentech" or "Defendant"), states as follows:

Parties, Jurisdiction and Venue

- 1. Oncology and Hematology Associates of Southwest Virginia, Inc. is a Virginia corporation doing business as Blue Ridge Cancer Care (hereinafter "BRCC" or "Plaintiff") with its principal place of business in Roanoke, Virginia.
- 2. Defendant Genentech Inc. ("Genentech") is a Delaware corporation with its principal place of business in San Francisco, California.
- 3. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because there exists complete diversity among each Plaintiff and the Defendant and the amount in controversy, exclusive of interest and costs, exceeds \$75,000.

- 4. This Court has personal jurisdiction over Defendant pursuant to Virginia Code § 8.01-328.1 because Defendant transacts business, including the business giving rise to the underlying transaction, in the Commonwealth of Virginia.
- 5. Venue in this Court is proper pursuant to 28 U.S.C. § 1391 and Local Rule 3(c) because a substantial part of the events or omissions giving rise to the claim of Plaintiff occurred in this judicial district and division and because Defendant is subject to this Court's personal jurisdiction.

Factual Allegations

Summary of the Plaintiff's Claims

- 6. Plaintiff provides healthcare services and specializes in the diagnosis and treatment of cancer. Plaintiff purchased a cancer treatment drug known as Herceptin which was manufactured and distributed by the Defendant Genentech. Plaintiff suffered damages caused by Genentech's breach of warranties concerning the advertising, labeling and delivery of the true volume and density of Herceptin available in the vials Plaintiff purchased.
- 7. Herceptin is distributed in containers (vials) which are represented by Genentech to contain 440 milligrams (mg) of lyophilized (dehydrated or "freeze-dried") medicine. To administer the medicine, the Herceptin product is mixed, pursuant to directions provided by Genentech, with a liquid (diluent), also provided to end users by Genentech. After mixing the lyophilized medicine and the diluent, Genentech claims the resulting fluid contains 440 mg of Herceptin at a concentration of 21 mg/mL.
 - 8. 440 mg concentrated at 21 mg/mL would provide 20.952 mL of fluid solution.
- 9. Upon information and belief, the actual volume yielded for use in treating patients is never more than 20.2 mL.

- 10. This shortage is caused either by a lower amount of Herceptin being provided than advertised or a higher concentration of Herceptin after mixing than advertised.
- 11. The 20.2 mL, rather than 20.952 mL, could be caused by Genentech providing 424 mg of Herceptin instead of the 440 mg represented and warranted by Genentech.
- 12. The 20.2 mL, rather than 20.952 mL, could be caused by Genentech inaccurately representing and warranting the concentration of the mixed fluid solution as 21 mg/mL when it really is 21.8 mg/mL.
- 13. Genentech's internal emails acknowledge that the represented concentration is not accurate. Genentech's Production Engineer explained to his internal audience that Genentech's own internal technical report showed a concentration of 21.8 mg/ml. *See* Email from Tom White to Olivia Ware and William Henry Smith (Sept. 25, 2002) (Ex. 1). However, Genentech made the calculated decision to represent the concentration as 21 mg/ml and thus require physicians and practice groups to buy more product.
- 14. Regardless the cause of the discrepancy, Plaintiff does not receive 20.952 mL of fluid solution after following Genentech's direction despite paying for the 20.952 mL quantity.

Plaintiff BRCC

15. At all times relevant to this action, BRCC was an independent cancer and hematology treatment practice serving patients in ten locations throughout southwest Virginia. For approximately 40 years, BRCC has helped patients with cancer and blood disorders get the most out of life.

Herceptin's Purpose

16. The cancer drug that forms the basis for the claims in this lawsuit is Herceptin (trastuzumab). Herceptin is used to treat patients with metastatic breast cancer and tumors that

overexpress the HER2 gene. Herceptin is widely-used and, with many patients, is an effective drug to reduce and deter the growth of malignant breast cells. Herceptin is approved by the FDA as an adjuvant therapy for breast cancer and for metastatic, gastric cancer which has tested positive for HER2 receptor sites.

- 17. The HER2 gene makes HER2 proteins, which are receptors on breast cells. Normally, HER2 receptors help control how a healthy breast cell grows, divides, and repairs itself. In about 25% of breast cancers, the HER2 gene fails to work correctly and makes too many copies of itself (known as HER2 gene amplification). The extra HER2 genes allow breast cells to make too many HER2 receptors; referred to as HER2 protein overexpression. This makes breast cells grow and divide in an uncontrolled way. Breast cancers with HER2 gene amplification or HER2 protein overexpression are called HER2-positive. HER2-positive breast cancers tend to grow faster and are more likely to spread and return after treatment compared to HER2-negative breast cancers.
- 18. Genentech manufactures and distributes Herceptin. Plaintiff has purchased Herceptin to use in the treatment of patients. Genentech also sends its own representatives to Plaintiff's offices.
- 19. Genentech markets itself as a research-driven corporation. Genentech employs more than 1,100 researchers, who cover a wide range of scientific activity-from molecular biology to protein chemistry, bioinformatics and physiology. Genentech scientists claim to focus their efforts on five disease categories including oncology, immunology, tissue growth and repair, neuroscience and infectious disease.
- 20. Genentech markets and distributes Herceptin through a closed distributor network. Genentech also administers rebate programs in which Plaintiff is a participant.

21. Herceptin is the only cancer medication currently on the market that effectively treats metastatic breast cancer and tumors that overexpress the HER2 gene.

Herceptin's FDA Approved Preparation Instructions

- 22. In 1998, Genentech submitted and the FDA approved a Label for Herceptin.
- 23. The 1998 FDA-approved Label provided a Preparation for Administration section that instructed: "Use appropriate aseptic technique. Each vial of HERCEPTIN should be reconstituted with 20mL of BWFI, USP, 1.1% benzyl alcohol preserved, as supplied, to yield a multi-dose solution containing 21 mg/mL Trastuzumab."
- 24. The FDA-approved Prescribing Information (or "Label") has been modified several times since 1998.
- 25. Each FDA-approved Prescribing Information for Herceptin included that same basic instruction, including the most recent April 2015 revised Prescribing Information: "Reconstitute each 440 mg vial of Herceptin with 20 mL of Bacteriostatic Water for Injection (BWFI), USP, containing 1.1% benzyl alcohol as a preservative to yield a multi-dose solution containing 21 mg/mL trastuzumab."
- 26. Herceptin is manufactured as a lyophilized (dehydrated and "freeze-dried" powder) medicine which is delivered in multi-dose vials, labeled by Genentech as containing 440 milligrams (mg) of Herceptin. The Herceptin product is mixed with a liquid (diluent), also provided to end users by Genentech. The mixing process is accomplished by injecting the diluent into the vial containing the lyophilized Herceptin. The typical single dose leaves other available medicine in the multi-dose vial, which most often is used as all or a portion of a dosage for a different patient.

- 27. This mixing process reconstitutes each vial of Herceptin into a multi-dose fluid solution.
- 28. Genentech represents and warrants that the resulting multi-dose fluid solution is concentrated at a density of 21 mg/mL.
- 29. 440 mg reconstituted into a fluid solution with a density of 21 mg/mL would result in 20.952 mL of fluid solution: 440 mg divided by 21 mg/mL.

The Herceptin Shortage

- 30. Plaintiff has discovered that it cannot obtain 20.952 mL of fluid solution by following the Preparation of Administration instructions provided by Genentech and approved by the FDA. The discovery of this shortage was made more difficult because of Genentech's decision to market Herceptin in multi-dose vials in the United States.
- 31. Plaintiff does not obtain more than 20.2 mL of fluid solution by following the Preparation of Administration instructions provided by Genentech and approved by the FDA.
- 32. These multi-dose vials were and are used by Plaintiff to administer Herceptin to patients based on each patient's prescribed treatment dosage.
- 33. The reconstituted Herceptin does not contain 440 mg of Herceptin and/or is not a fluid solution with a concentration greater than 21 mg/mL.
- 34. Plaintiff relied upon Genentech's representation that the concentration of the fluid solution is 21 mg/mL when administering the proper dosage to each patient. In administering the Herceptin from the multi-dose vials, Plaintiff withdraws the amount of reconstituted Herceptin medicine necessary for each patient until each vial is emptied.
- 35. Relying on Genentech's representation that the fluid solution density is 21 mg/mL, Plaintiff provides sufficient volume of the fluid solution to administer the proper dosage

of Herceptin. For example, a person weighing 50 kg should receive 200 mg of Herceptin for her initial dose. To administer 200 mg of Herceptin, Plaintiff would provide 9.52 mL of fluid solution: 200 mg divided by 21 mg/mL.

- 36. If Genentech's representation that the fluid solution density is 21 mg/mL is accurate, then Genentech is providing, at most, 424 mg of Herceptin: 20.2 mL multiplied by 21 mg/mL. If Genentech is providing 424 mg or less of Herceptin, Genentech is providing less medicine than represented and warranted, and causing Plaintiff to purchase additional Herceptin.
- 37. If Genentech's representation that the Herceptin vial contains 440 mg of Herceptin is accurate, then the fluid solution density is, at least, 21.8 mg/mL: 440 mg divided by 20.2 mL. If Genentech is providing instructions and product that create a fluid solution density of at least 21.8 mg/mL, Genentech is causing Plaintiff to administer an overdose by representing the fluid solution density is 21 mg/mL, and causing Plaintiff to purchase additional Herceptin.
- 38. Either way, Plaintiff is forced to purchase additional Herceptin because following Genentech's Preparation of Administration instructions yields less volume of fluid solution than mathematically follows from Genentech's representation and warranties.

Count I: Breach of Express Warranty

Plaintiff adopts the allegations contained in paragraphs 1 through 38 and further alleges and states:

- 39. Plaintiff relied on all representations and warranties made by Genentech concerning the quantity of Herceptin purchased from Genentech.
- 40. Plaintiff relied on all representations and warranties made by Genentech concerning the density of the fluid solution of reconstituted Herceptin purchased from Genentech.

- 41. Reconstituting each vial of Herceptin yields no more than 20.2 mL rather than the 20.952 mL that is represented by Genentech's own warranties.
- 42. Genentech's representations and warranties were made for the benefit of Plaintiff, were material to Plaintiff, and were material to its purchase and use of Herceptin.
 - 43. Genentech's false representations and warranties relied upon by Plaintiff includes:
 - a. Each vial purchased by Plaintiff contains 440 mg of Herceptin.
 - b. Each reconstituted vial of Herceptin yields fluid solution with a density of 21 mg/mL.
 - c. Each reconstituted vial of Herceptin contains 20.952 mL of fluid solution.
- 44. As a result of Genentech's breach of express warranty, Plaintiff has been and continues to be damaged due to the additional vials of Herceptin it was and is forced to purchase.

Count II: Breach of Implied Warranty

Plaintiff adopts the allegations contained in paragraphs 1 through 44 and further alleges and states:

- 45. Under the implied warranty of merchantability, Genentech was required to provide goods that were consistent in kind, quality, and quantity with the representations concerning the Herceptin product.
- 46. Genentech breached its warranty of merchantability by providing Plaintiff with Herceptin that did not meet the quantity represented and warranted for the benefit of Plaintiff by Genentech.
- 47. As a result of Genentech's breach of implied warranty, Plaintiff has been and continues to be damaged due to the additional vials of Herceptin it was and is forced to purchase.

Count III: Unjust Enrichment

Plaintiff adopts the allegations contained in paragraphs 1 through 47 and further alleges and states:

- 48. Genentech has received and continues to receive an unfair benefit through its practice of providing vials and product that yield only 20.2 mL of usable Herceptin fluid solution, but receiving payment for 20.952 mL of product for each vial sold.
- 49. Genentech knew of this benefit and should have reasonably expected to repay Plaintiff.
 - 50. Genentech accepted and retained the benefit without paying for its value.
- 51. Under the circumstances, as alleged herein, the retention of that benefit would unjustly enrich Genentech.
- 52. The Plaintiff has suffered economic damages while Genentech has enjoyed unjust enrichment.

Request for Relief

WHEREFORE, Plaintiff respectfully request the following relief:

- 1. Entry of a judgment for Plaintiff against Genentech for all damages it has suffered through the date of judgment as a result of Genentech's activities and conduct;
 - 2. All other relief as this Court may determine Plaintiff is entitled to receive.

Respectfully Submitted,

ONCOLOGY AND HEMATOLOGY ASSOCIATES OF SOUTHWEST VIRGINIA, INC., a Virginia Corporation, dba BLUE RIDGE CANCER CARE

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